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**13. Abstract** ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

During the past year, we obtained IRB approval from the DOD to begin data collection in December, 2001. However, the practice of the Breast Health Center, where the study was planned, had changed. Because randomization of patients according to core biopsy scheduling was no longer, we had a series of meetings with the Breast Health Center and Siteman Cancer Center administrators. At these discussions, we decided to revise the protocol. The revised protocol is submitted. Patients will still be randomized into different groups based on the informed consent process, but the timing of the core biopsy would not be manipulated. We still plan to collect observational data on this variable, however. Currently, we are seeking IRB approval of the revised protocol. Once this protocol is approved by the IRB's of both Washington University and DOD, we can begin data collection. The revision of the protocol has led to significant delays in the second phase of this project.

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## Table of Contents

## Introduction

My Statement of Work (Appendix A) is a series of pilot projects addressing information needs and educational issues for women with breast disease. In addition to providing valuable experience, the projects will help generate hypotheses and data for larger studies in the future. The Statement of Work (Appendix A) also includes opportunities to acquire skills in developing patient educational materials, both in the classroom setting and by participating in projects. There are two main objectives: 1) To obtain practical experience with patient outreach and educational program development for breast patients; and 2) To further develop public health research skills by conducting a series of small projects in the field of breast imaging, with an emphasis on the educational needs of underserved women.

## Body

*Tasks 1-3, 5: Breast Cancer: Dealing with the Diagnosis*

These tasks were completed in 2001. This information is included in the last annual report.

*Tasks 4 and 6: Health Promotion Program Planning and Evaluation Courses*

In January, 2002, I attended a course at Saint Louis University School of Public Health on Health Promotion Program Planning (BSH-C510) taught by Marshall Kreuter, PhD. The 50 hour course covered theoretical models for health promotion programs and practical exercises. The second part of this course will likely be offered in spring, 2003.

*Task 7: Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes.*

During the past year, We obtained IRB approval from the DOD to begin data collection in December, 2001. However, the practice of the Breast Health Center, where the study was planned, had changed. Because randomization of patients according to core biopsy scheduling was no longer feasible. After a series of meetings with the Breast Health Center and Siteman Cancer Center administrators, we decided to revise the protocol. The revised protocol is in the appendix. Patients will still be randomized into different groups based on the informed consent process, but the timing of the core biopsy would not be manipulated. We still plan to collect observational data on this variable, however. Currently, we are seeking IRB approval of the revised protocol. Once this protocol is approved by the IRB's of both Washington University and DOD, we can begin data collection. The revision of the protocol has led to significant delays in the second phase of this project.

## Key Research Accomplishments

- Development of breast cancer educational tool for doctors and patients in the clinic setting
- Development of low literacy handbook for newly diagnosed breast cancer patients. To date, more than 150 handbooks distibuted to Sat. Louis area patients.
- Development of video addressing coping mechanisms for women newly diagnosed with breast cancer- targets African-American women. To date, more than 150 handbooks distibuted to Sat. Louis area patients.

## Reportable Outcomes

1. Siteman Cancer Center Research Development Award ($50,000)
   Project: Evaluating the Effect of Informed Consent and Procedure Scheduling of Breast Biopsy Patient Outcomes, June 1, 2000- May 31, 2002 (Second year of funding awarded 6/4/2001.)
2. Schmidt ME, Farria DM, Bokern JF. One Step at a Time: Dealing with Breast Cancer. ( Handbook for newly diagnosed breast cancer patients)
3. Schmidt ME, Farria DM, Bokern JF. Between Friends: Dealing with Breast Cancer. (Video for newly diagnosed breast cancer patients)
4. Farria DM, Schmidt ME, Bokern JF. Breast Diagnosis and Treatment Flipchart (Breast patient educational tool for clinic setting)

## Conclusions

Tasks 1-5 have been completed. This year, we encountered delays in instituting the data collection phase, because the protocol was revised. The changes are minor. We are in the process of obtaining IRB approval for the revised protocol.

## References

None

## Appendices

A. Original Statement of Work

B. Revised Statement of Work

C. Revised Protocol

**Dione Farria, MD, MPH**

**Objectives**

1. To obtain practical experience in patient outreach and educational program development for breast imaging and breast cancer patients
2. To further develop public health research skills by conducting a series of small projects in the field of breast imaging, with an emphasis on the educational needs of underserved women

**Dione Farria, MD, MPH**
**Statement of Work: Education and Outreach for Breast Imaging and Breast Cancer Patients**

**Months 1-3** **Task 1**: *Breast Cancer: Dealing with the Diagnosis: Part 1 (Research and Development)*
This educational project is a cooperative effort of Barnes-Jewish Breast Health Center and Fleishman-Hillard International Communications Firm. The project involves the development of a free educational handbook and video for low literacy minority St. Louis women with a new diagnosis of breast cancer. I will function as co-director of this project.

a) Handbook research and development
   - Research existing materials
   - Develop text outline and overall format
   - Identify/ develop illustrations for use in manual
   - Write draft of text and revise with literacy consultant (approximately 20 pages at 6th to 8th grade reading level)

b) Video research and development
   - Research existing video materials
   - Meet with breast cancer survivors to identify key messages for video
   - Develop script outline and overall format (approximately 5-7 minutes)

**Months 4-6** **Task 2:** *Breast Cancer: Dealing with the Diagnosis: Part 2 (Production)*

a) Handbook (Produce 1000 copies)
   - Revise and edit text and illustrations
   - Obtain feedback on draft from 5 representatives of target audience through one-on-one discussions
   - Obtain feedback on draft from advisory panel members (breast cancer survivors, surgeons, radiologists, psychologists, social workers)
   - Produce 1000 handbooks
   - Develop preliminary distribution and promotion plan

b) Video (Produce 300 copies)
   - Select narrator and speakers for video
   - Revise and edit script
   - Film video and edit as needed
   - Obtain feedback on draft from target audience and advisory panel
   - Develop preliminary distribution and promotion plan

**Months 7-8** **Task 3**: *Breast Cancer: Dealing with the Diagnosis: Part 3 (Distribution and Assessment)*
   - Promotion of products
   - Distribution free of charge to local women and clinics
   - Assess satisfaction with products by interviewing 20-30 women (10-15 who used the video and 10-15 who used the handbook)

**Months 6-8** **Task 4**: *Health Promotion Program Planning (St. Louis University School of Public Health)*
I will attend 5 class sessions (total of 40 hours) which introduce the discipline of health education, including needs assessment, program planning, implementation and evaluation.

**Months 9-14** **Task 5**: *Improving Physician Communication with Breast Biopsy Patients: Phase I*
The first phase of this project is the development of an educational flip chart for physicians to use in the office setting when discussing breast biopsy and treatment options with patients.

a) Focus group testing of women who have had a breast biopsy and breast cancer survivors to guide the content of the flip chart
b) Develop outline and overall format
c) Identify/develop illustrations and photographs for use in flip chart
d) Obtain feedback from radiologists, breast cancer surgeons, and women who have had breast biopsies
e) Obtain IRB approval for Phase 2

**Months 9-11** **Task 6**: *Health Promotion Program Evaluation (St. Louis University School of Public Health)*
I will attend 5 class sessions (total of 40 hours) which cover the principles and procedures used to evaluate health promotion and disease prevention programs.

**Months 15-23** **Task 7:** *Improving Physician Communication with Breast Biopsy Patients: Phase 2*
The second phase is a randomized trial, which assesses the utility of the flip chart in radiologist-patient discussions about imaging-guided breast procedures. Using patient surveys of women having imaging-guided biopsies, I will assess the impact of the educational tool on the following outcomes: 1) patient anxiety; 2) fulfilled expectations of the biopsy; 3) basic understanding of the procedure; and 4) patient satisfaction with the procedure.

a) Develop survey instruments for three timepoints: baseline, after discussion of procedure, and after biopsy.
b) Pilot survey in sample of 10 women.
c) Survey approximately 100 women.

**Months 24-27** **Task 8:** *Improving Physician Communication with Breast Biopsy Patients: Phase 3*

a) Data entry and programming
b) Data analysis using bivariate analysis and logistic regression
c) Manuscript preparation

**Months 28-33** **Task 9:** *Mammography Screening Practices of High Risk African-American Women: Phase I (Survey design)* This project is an exploratory study to assess the information needs and mammography screening patterns of African-American women who have a family history of breast cancer.

a) Obtain IRB approval
b) Focus testing of three groups of women (women with no family history, women with weak family history, and women with strong family history of breast cancer) to guide survey design.
c) Develop survey to assess characteristics of 3 groups ( evaluate anxiety regarding breast cancer, compliance with mammography screening guidelines, and knowledge about personal breast cancer risk)

**Months 34-42** **Task 10**: *Mammography Screening Practices of High Risk African-American Women: Phase 2 (Data collection)*

a) Conduct pilot test of survey on 10 women
b) Conduct surveys
c) Data entry, programming, and analysis using multivariate regression
d) Manuscript preparation

**Months 43- 48** **Task 11**: *Mammography Screening Practices of High Risk African-American Women: Phase 3(Tailored Educational Materials)*

a) Develop an educational pamphlet based on survey results which is tailored to African-American women who have a family history of breast cancer.
b) Distribute via African-American health clinics, support groups and organizations.

**Note:** If time permits, I will conduct a pilot study, entitled *Improving Afro-American Participation in Breast Imaging and Breast Cancer Clinical Trials.* This task will include:

a) Identify all breast cancer related clinical trials at Washington University Medical School. Obtain information on sample size, patient demographics, age and socioeconomic status.
b) Conduct 2 focus groups: one with African-American women who have participated in a clinical trial and one with African-American women who have refused participation in a clinical trial.
c) Based on focus group data, identify an educational intervention to increase African-American participation in clinical trials. Apply for funding to test new intervention.

**REVISED STATEMENT OF WORK:**

**Dione Farria, MD, MPH**
**Statement of Work: Education and Outreach for Breast Imaging and Breast Cancer Patients**

**Months 1-3** **Task 1**: *Breast Cancer: Dealing with the Diagnosis: Part 1 (Research and Development)*
This educational project is a cooperative effort of Barnes-Jewish Breast Health Center and Fleishman-Hillard International Communications Firm. The project involves the development of a free educational handbook and video for low literacy minority St. Louis women with a new diagnosis of breast cancer. I will function as co-director of this project.

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   - Develop script outline and overall format (approximately 5-7 minutes)

**Months 4-6** **Task 2:** *Breast Cancer: Dealing with the Diagnosis: Part 2 (Production)*

a) Handbook (Produce 1000 copies)
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**Months 6-8** **Task 4**: *Health Promotion Program Planning (St. Louis University School of Public Health)*
I will attend 5 class sessions (total of 40 hours) which introduce the discipline of health education, including needs assessment, program planning, implementation and evaluation.

**Months 9-17** **Task 5**: *Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes*
The first phase of this project is the development of an educational flip chart for physicians to use in the office setting when discussing breast biopsy and treatment options with patients.

a) Focus group testing of women who have had a breast biopsy and breast cancer survivors to guide the content of the flip chart
b) Develop outline and overall format
c) Identify/develop illustrations and photographs for use in flip chart
d) Obtain IRB approval for Phase 2

**Months 18-20** **Task 6:** *Health Promotion Program Evaluation (St. Louis University School of Public Health)*
I will attend 5 class sessions (total of 40 hours) which cover the principles and procedures used to evaluate health promotion and disease prevention programs.

**Months 21-30** **Task 7:** *Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase 2*
The second phase is a randomized trial, which assesses the utility of the flip chart in radiologist-patient discussions about imaging-guided breast procedures. Using patient surveys of women having imaging-guided biopsies, I will assess the impact of the educational tool on the following outcomes: 1) patient anxiety; 2) fulfilled expectations of the biopsy; 3) basic understanding of the procedure; and 4) patient satisfaction with the procedure. The protocol will be revised during this task.

a) Revise survey instruments.
b) Re-obtain Protocol Review Monitoring Committee and IRB approval at Washington U. and DOD.

**Months 31-42** **Task 8:** *Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase 2*

a) Data collection
b) Data entry

**Months 43-48** **Task 9:** : *Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase 2*

a) Data analysis
b) Manuscript preparation

The proposed study is a two-year project, and the design, background, and specific aims presented in this application reflect the overall goals of the study

**A. Specific Aims**

Aim 1 We will evaluate the effect of using a visual educational tool on the validity of informed consent for breast biopsy, as measured by the patient's factual knowledge related to the biopsy.

Aim 2 We will evaluate the effect of the timing of breast biopsy performance on patient satisfaction with the overall biopsy experience, including the patient's perceptions of either excessive coercion or unnecessary delay in the diagnostic evaluation.

Aim 3 We will evaluate the effects of the educational tool and the timing of the biopsy on a) reducing patient anxiety related to the biopsy; b) enhancing patient satisfaction with the biopsy experience; and c) increasing self-reported (subjective) understanding of the procedure.

Aim 4 We will explore the relationships among the interventions, patient anxiety, factual knowledge, subjective understanding and satisfaction with the biopsy experience

**Significance to Cancer Research**

In the United States, approximately 1.2 million breast biopsies are performed annually, including approximately 330,000 image-guided core biopsies.[1] These minimally invasive procedures, which include stereotactic and ultrasound-guided biopsies, are proven cost-effective alternatives to surgical biopsies.[2] Core biopsies have revolutionized patient care by decreasing the time between detection and diagnosis, reducing the costs and morbidity of breast biopsies, and decreasing the number open surgical procedures needed for both benign and malignant disease.[2,3] However, since image guided core biopsies have been in widespread clinical use for less than a decade, some quality of care issues have not been fully addressed:

1) *Patient information needs*. Currently, it is unclear if patients' pre-biopsy information needs are adequately met by the standard informed consent process.
2) *Patient anxiety*. Although studies have shown a correlation between a patient's lack of understanding of a breast biopsy procedure and higher reported anxiety levels, no interventions have been tested to increase patient understanding and decrease anxiety related to the procedure.[4,5]
3) *Appropriate timing of procedures*.. There are wide variations in the timing of breast biopsies. Some facilities advocate same-day diagnosis, where a woman can receive her diagnostic breast imaging work-up and core biopsy all within several hours. At other facilities, patients wait longer periods, ranging from a few days to several weeks, to obtain a biopsy after a mammographic abnormality is detected. The impact of the timing of the breast biopsy on patient anxiety, satisfaction, and understanding of the procedure has not been studied. Furthermore, we do not know if the information needs for women in the same day diagnosis group differ from women who obtain their biopsy on a later visit.

This project will provide valuable information on the breast biopsy experience from the patient's perspective, assess the validity of the current informed consent process, and evaluate the effects of biopsy scheduling on patient outcomes. In addition, the data from this study will be valuable in developing a conceptual model to better understand the relationships between key aspects of clinical management (biopsy scheduling, informed consent) and breast biopsy patient outcomes (anxiety, satisfaction, knowledge). This preliminary theoretical framework may be relevant in other cancer patient populations as well. In addition, this study will provide a practical educational tool, which will facilitate doctor-patient communication in the breast clinic setting.

*Cancer Center Collaborations*

This project will be a collaborative effort of the Barnes-Jewish Breast Health Center and the Psychosocial Core of the Alvin J. Siteman Cancer Center. Mark Walker, PhD is a member of the Psychosocial Core, who will serve as co-investigator on this project. He is a psychologist in the Division of Health Behavior Research, who will play an active role in research design, survey instrument development, and statistical data analyses. The Health Communication Research Laboratory of St. Louis University School of Public Health, a component of the Psychosocial Core, will develop the educational intervention for use in this study. This group will be responsible for graphics, photo shoots, design and production of the educational tool, under the guidance of the study principal and co-investigators.

**Background and Preliminary Investigations**

*Informed Consent*

For most procedures, informed consent is obtained during an unstructured verbal encounter between the provider and the patient, with a written document requiring the patient's signature. This traditional method of informed consent has been studied for some procedures. These studies have shown relatively poor understanding of the proposed procedure. Olver et al[6] interviewed 100 patients having chemotherapy after obtaining informed consent. Only 34 patients understood the purpose of the written informed consent document; and 26 did not know the goal of their therapy. Only one patient considered the written document a major source of information about the procedure. In Montgomery's study, 25% of patients could not recall being told side effects during the consent process for radiotherapy; 28% were unhappy with the amount of information offered prior to the procedure.[7] Currently, there are no studies which assess whether the breast biopsy patient receives adequate information during informed consent.

Although the results of 80% of breast biopsies are benign, the procedure is associated with emotional distress.[8] Studies have shown that women awaiting excisional breast biopsies, experience anxiety levels exceeding those of patients undergoing other types of elective surgery.[9] For core breast biopsies, high anxiety levels are also reported. These anxiety levels appear to be related to the patient's understanding of the planned procedure. In one study of 52 women, Maxwell[10] reported anxiety levels that were significantly higher than levels reported in general medical and surgical patients, similar to anxiety levels found in acute neuropsychiatric admission patients. Women experienced less pre-procedure anxiety if they were over 50 years old, married, or had a greater understanding of the core biopsy procedure. Handy et al[4] showed a statistically significant correlation between a patient's lack of understanding regarding the procedure and the patient's expected level of discomfort. Other studies have had similar results.

Based on a review of the literature, the educational intervention proposed in our study will likely increase the patient's knowledge about the procedure because: 1) More detailed information will be provided. Prior studies have shown that providing more detailed information during informed consent increases the patient's factual knowledge without increasing patient anxiety. Dawes et al,[11] based on a study of 190 patients scheduled for ENT surgery, reported that using a structured interview for informed consent increased factual knowledge, without increasing patient anxiety. Kerrigan[12] actually found a decrease in patient anxiety in patients who received detailed information about a planned inguinal hernia repair, suggesting some degree of reassurance in learning more before a procedure. 2). Luck[13], in a study of 150 subjects reported greater knowledge regarding the purpose of the procedure, procedural details and potential complications in patients exposed to the educational intervention. The treatment group also had less pre-procedural anxiety. Agre at al[14] had similar results. Like a video, the flipchart will add a visual component and more structure to the informed consent discussion. At least two studies showed an increase in factual knowledge by adding a video to the informed consent process for colonoscopy.

*Timing of Breast Biopsies*

The scientific literature has limited data on the effects of biopsy scheduling on patient outcomes. It is unclear if the current method of informed consent adequately prepares a patient for a rapid diagnostic work-up, such as a biopsy performed the same day as the mammographic examination. Allegheny General Hospital in Pittsburgh reports that 75% of their patients opt for a breast biopsy the same day as the mammogram, but a susbset of patients need more time.[15] For some women, a rapid diagnostic process may add anxiety, decrease the ability of the patient to assimilate information, and limit the time for the patient to generate needed support from family and friends. On the other hand, delays in obtaining a diagnosis may add stress for some women. The majority of breast cancer patients recall the diagnostic phase as the most stressful part of their experience, more stressful than the actual

treatment or recovery. In a study of 238 women with benign biopsies, 58% recalled severe anxiety during the period from discovery to diagnosis.[16] More data is needed on the information needs of women in relation to the timing of diagnostic procedures. The proposed study will address some of these gaps in the literature, as well as generate pilot data on the effects of biopsy scheduling on key patient outcomes.

*Donabedian Model of Quality Assessment*

This study will add to the body of literature on quality of care issues in medicine. According to Donabedian,[17] quality of health care is defined in three areas- stucture (e.g. staffing, physical facility, etc), process (e.g., interpersonal communication of providers, technical skills, etc) and outcomes (e.g., patient morbidity, patient satisfaction, adherence to provider recommendations, etc). Based on Donabedian's framework for healthcare quality assessment, we will evaluate two process of care factors- the informed consent process and biopsy schedulinh. We will evaluate how these two elements affect patient outcomes in three main areas of psychosocial effectiveness:[18]

a) cognitive- factual knowledge related to the procedure
b) attitudinal- patient satisfaction, subjective understanding
c) behavioral- anxiety.

**Experimental Design and Methods**

*Revised Project Design*

Subjects will be randomized into two main groups: the interventional group who are exposed to the educational tool and the control group, who are not exposed to the educational tool during informed consent. Patients will be surveyed at three timepoints: prior to the procedure informed consent, after the procedure informed consent, and immediately after the biopsy. The outcome measures are patient anxiety related to the procedure, factual knowledge, subjective understanding of the procedure, and patient satisfaction with the biopsy process. The interviews at each timepoint will take approximately 10 minutes, and will be administered by a trained research staff person. Four board certified radiologists will conduct the informed consent discussions for both intervention and control groups. We will audiotape the informed consent discussions to assure standardization of content. The incentive for participants for this part of the study is $10, which will be paid after the biopsy and interviews are completed.

To explore issues regarding the timing of breast core biopsies, we will collect data on the amount of time each subject waited to have a biopsy, her biopsy timing preferences, and patient satisfaction with the timing of the procedure. This data will be collected as a written survey, which is completed after the biopsy. The timing of the biopsy will not be manipulated during this study, but will be collected as observational data.

Eligible subjects are women at BJC Breast Health Center who are recommended for an imaging-guided core biopsy (stereotactic or ultrasound-guided core biopsy). Women who have a prior history of breast cancer will be excluded from the study. For a sample size of 125 subjects, based on a 30% refusal rate, data collection will last 6 months. (The BJC Breast Health Center performs 350 image-guided core biopsies annually.)

*Data Analysis*

Descriptive statistics (e.g., means, standard deviations) will be generated for all data. The primary analyses regarding each of the specific aims are outlined below:

Specific Aims 1-3: ANCOVA will be employed to test for main and interaction effects of the educational intervention and timing of the biopsy on post-consultation anxiety, post-consultation factual and subjective knowledge, and post-biopsy satisfaction. . Demographic variables, family history of breast cancer, baseline anxiety, baseline knowledge, and type of biopsy (ultrasound vs. stereotactic) will serve as potential covariates for these analyses.

Specific Aim 4: Structural equation modeling will be used to evaluate the fit of the data to a model of the relationships among treatment conditions, anxiety, factual knowledge, subjective understanding and post-biopsy satisfaction. The model will be tested against a reduced model in which direct effects of treatment conditions on anxiety, satisfaction and subjective sense of understanding are fixed to zero.

For sample size considerations, we assumed a moderate effect size on the primary outcome variables of anxiety, objective and subjective knowledge, and satisfaction. In a simple test of the difference between means, this corresponds to an effect size *d* of .50, and is less than the effect sizes observed in other brief interventions aimed at reducing anxiety in a similar population.[19,20] With the projected sample size of 125, this would result in sample power of .79 for two-sided significance tests at the .05 level. However, this does not take into account the anticipated effects of the covariates, including demographic variables, type of biopsy, baseline anxiety and baseline knowledge. If these covariates account for just 10% of the variance of the outcome variable, we would have power of .97 to detect an increment of 10% in explained variance for two-sided significance tests at the .05 level. In addition, we vastly exceed the recommended 10:1 case to variable ratio with 9 variables in the model.

For the structural equational models, Figure 1 includes 24 freely estimated parameters. According to Bentler,[21] a case to freely estimated parameter ratio of 5:1 may be adequate for testing structural models under normal distribution theory. Given the number of parameters in our model and our projected sample size of 125, we should have adequate power to evaluate the model under consideration (Figure 1).

*Future Aims*

The pilot data generated from this study will provide a basis for future investigations, especially when applying for funding from NIH and other extramural sources. Three possible future investigations are outlined below: 1) In this era when cost containment is receiving increasing attention, this study may lead to a larger study, which explores alternative methods for delivering pre-procedural information to patients. For example, computer technology or a non-physician provider may deliver the factual content of our educational tool in a more cost-effective manner. 2) The information we learn about improving the informed consent process from this study may be applicable to other clinical settings. 3) Our educational tool will be useful in a number of clinical and research settings, such as discussion of breast biopsy choices, informed consent for diagnostic procedures, and discussion of treatment options. In the literature, there is preliminary data that a similar educational tool used during the medical consultation enhances the patient's decisionmaking abilities.[22] Therefore, our educational tool may also be tested as a decision aid for patients considering biopsy or treatment options.

**Modification of Protocol**

<u>All modifications to the protocol, consent form and/or questionnaires must be submitted to the Human Subjects Review Board for review and approval prior to implementation. A list if proposed modifications or amendments to the protocol and an explanation of the need for these modifications should be submitted. The level of review required for approval depends on the nature of the modifications.</u>

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Table I

| *Outcome* | *Measure* | *Timing of Measure* |
|---|---|---|
| Validity of informed consent | Will design a survey to obtain patient's factual knowledge of procedure. | 1. Baseline- prior to conser<br>2. After informed consent |
| Patient anxiety related to procedure | a. Spielberger State Anxiety Inventory.<br>b. One question rating anxiety or scale<br>of 1-10. | 1. Baseline<br>2. After informed consent<br>3. Immediately after procedure |
| Patient satisfaction with biop experience | We adapted a psychometrically v survey, which is used in the BJC Breast Health Center. | Immediately after procedu |
| Subjective understanding of procedure | Will design a survey to assess patient's<br>impression of their understandin the procedure. | 1. Baseline<br>2. After informed consent<br>3. Immediately after procedure |